Complete Summary

GUIDELINE TITLE

Daytime lower urinary tract conditions. In: Guidelines on paediatric urology.

BIBLIOGRAPHIC SOURCE(S)

Daytime lower urinary tract conditions. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr Chr, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2009 Mar. p. 26-9. [19 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Daytime lower urinary tract conditions. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 29-32.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

August 3, 2009 - Onabotulinum toxin A (Botox/Botox Cosmetic),
 Abobotulinum toxin A (Dysport) and Rimabotulinum toxin B (Myobloc): The
 U.S. Food and Drug Administration (FDA) notified healthcare professionals of
 changes to the established drug names for Botox/Botox Cosmetic, Dysport
 and Myobloc to reinforce individual potencies and prevent medication errors,
 and provided recommendations for healthcare professionals to consider, plus
 information for patients, family members, and caregivers.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Daytime lower urinary tract conditions including:

- Urge
- Incontinence
- Weak stream
- Hesitancy
- Frequency
- Urinary tract infection

Note: These conditions are considered in the absence of overt uropathy or neuropathy.

GUIDELINE CATEGORY

Counseling Diagnosis Evaluation Management Screening Treatment

CLINICAL SPECIALTY

Pediatrics Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To outline a practical and preliminary approach to paediatric urological problems
- To increase the quality of care for children with urological problems

TARGET POPULATION

Children and adolescents with daytime lower urinary tract conditions not associated with uropathy or neuropathy

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. History: structured interview
- 2. Assessment of signs and symptoms
- 3. Clinical examination
- 4. Use of a voiding diary
- 5. Uroflow with post-void residual retention assessment
- 6. Upper urinary tract ultrasound
- 7. Pad test
- 8. Video-urodynamic studies
- 9. Cystoscopy
- 10. Magnetic resonance imaging of lumbosacral spine and medulla
- 11. Psychological screening

Treatment/Management

- 1. Lower urinary tract rehabilitation (standard urotherapy)
- 2. Specific interventions
 - Physiotherapy
 - Biofeedback
 - Alarm therapy
 - Neurostimulation
 - Pharmacotherapy: antispasmodics, anticholinergics, antimuscarinics, alpha-blocking agents, botulinum toxin

MAJOR OUTCOMES CONSIDERED

- Normalization rate of bladder storage and voiding
- Daytime control of bladder function

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guidelines were based on current literature following a systematic review using MEDLINE.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- **1a** Evidence obtained from meta-analysis of randomized trials
- **1b** Evidence obtained from at least one randomized trial
- **2a** Evidence obtained from at least one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Application of a structured analysis of the literature was not possible due to a lack of well-designed studies. Whenever possible, statements have been classified in terms of level of evidence and grade of recommendation. Due to the limited availability of large randomized controlled trials – influenced also by the fact that a considerable number of treatment options relate to surgical interventions on a large spectrum of different congenital problems — this document is therefore largely a consensus document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

- The first step in the European Association of Urology (EAU) guidelines procedure is to define the main topic.
- The second step is to establish a working group. The working groups comprise about 4-8 members, from several countries. Most of the working group members are academic urologists with a special interest in the topic. In general, general practitioners or patient representatives are not part of the working groups. A chairman leads each group. A collaborative working group

- consisting of members representing the European Society for Paediatric Urology (ESPU) and the EAU has gathered in an effort to produce the current update of the paediatric urology guidelines.
- The third step is to collect and evaluate the underlying evidence from the published literature.
- The fourth step is to structure and present the information. The strength of the recommendation is clearly marked in three grades (A-C), depending on the evidence source upon which the recommendation is based. Every possible effort is made to make the linkage between the level of evidence and grade of recommendation as transparent as possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

There is no formal external review prior to publication.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was used to analyse and assess a range of specific attributes contributing to the validity of a specific clinical guideline.

The AGREE instrument, to be used by two to four appraisers, was developed by the AGREE collaboration (www.agreecollaboration.org) using referenced sources for the evaluation of specific guidelines. (See the "Availability of Companion Documents" field for further methodology information).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (1a-4) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Definition

Daytime lower urinary tract (LUT) conditions are conditions that present with LUT symptoms (LUTS), including urge, incontinence, weak stream, hesitancy, frequency and urinary tract infections, but without overt uropathy or neuropathy.

Normal bladder storage and voiding involves low pressure and adequate bladder volume filling. This is followed by a continuous detrusor contraction, which results in complete bladder emptying, associated with an adequate relaxation of the sphincter complex. Normal urine storage by the bladder and evacuation are controlled by a complex interaction between the spinal cord, brain stem, midbrain and higher cortical structures, associated with a complex integration of sympathetic, parasympathetic and somatic innervations.

It is understandable that this complex control mechanism is likely to be susceptible to developing different types of dysfunction. Various functional disorders of the detrusor-sphincter complex may occur during the sophisticated early development of normal mechanisms of micturition control. Voiding dysfunction is therefore thought to be the expression of incomplete or delayed maturation of the bladder sphincter complex.

Normal daytime control of bladder function matures between 2 and 3 years of age, while night-time control is normally achieved between 3 and 7 years of age. There are two main groups of voiding dysfunction, namely, filling-phase dysfunctions and voiding-phase dysfunctions.

Filling-Phase Dysfunctions

In filling-phase dysfunctions, the detrusor can be overactive, as in **overactive bladder (OAB) and urge syndrome**, or underactive, as in **underactive or highly compliant bladder** (formerly known as 'lazy bladder'). Furthermore, some children habitually postpone micturition leading to **voiding postponement**.

Voiding-Phase (Emptying) Dysfunctions

In voiding-phase (emptying) dysfunctions, interference with the sphincter and pelvic floor during detrusor contraction is the main dysfunction. The general term for this condition is **dysfunctional voiding**. Different degrees of dysfunction are described, depending on the strength of interference with the sphincter and pelvic floor. Weak interference results in staccato voiding, while stronger interference results in interrupted voiding and straining, due to an inability to relax during voiding.

Bladder sphincter dysfunction is often associated with bowel dysfunction such as obstipation and soiling. Sometimes, secondary anatomical changes are observed, such as trabeculation, diverticulae and vesicoureteral reflux.

Diagnosis

A non-invasive screening, consisting of history-taking, clinical examination, uroflow, ultrasound and voiding diary, is essential to reach a diagnosis.

In the paediatric age group, where the history is taken from both the parents and child together, a structured approach is recommended using a questionnaire. Many signs and symptoms related to voiding and wetting will be unknown to the parents and should be specifically requested, using the questionnaire as a checklist. A voiding diary is mandatory to determine the child's voiding frequency and voided volumes as well as the child's drinking habits. History-taking should also include assessment of bowel function. Some dysfunctional voiding scores have recently been developed and validated.

Upon clinical examination, genital inspection and observation of the lumbosacral spine and the lower extremities is necessary to exclude obvious uropathy and neuropathy. Uroflow with post-void residual evaluates the emptying ability, while an upper urinary tract ultrasound screens for secondary anatomical changes. A voiding diary provides information about storage function and incontinence frequency, while a pad test can help to quantify the urine loss.

In the case of resistance to initial treatment, or in the case of former failed treatment, re-evaluation is warranted and further video-urodynamic studies may be considered. Sometimes, there are minor, underlying, urological or neurological problems, which can only be suspected using video-urodynamics.

In the case of anatomical problems, such as urethral valve problems, syringocoeles, congenital obstructive posterior urethral membrane (COPUM) or Moormann's ring, it may be necessary to perform further cystoscopy with treatment. If neuropathic disease is suspected, magnetic resonance imaging (MRI) of the lumbosacral spine and medulla can help to exclude tethered cord, lipoma or other rare conditions.

Psychological screening may be useful for children or families with major psychological problems associated with the voiding dysfunction.

Treatment

Treatment of voiding dysfunction consists of lower urinary tract rehabilitation, mostly referred to as urotherapy. Urotherapy means non-surgical, non-pharmacological, treatment of LUT function. It is a very broad therapy field, incorporating many treatments used by urotherapists and other healthcare professionals. Urotherapy can be divided into standard therapy and specific interventions.

Standard Therapy

Standard urotherapy, which is defined as non-surgical, non-pharmacological, treatment for LUT malfunction, includes the following components:

- Information and demystification, which includes explanation about normal LUT function and how a particular child deviates from normal function
- Instruction about what to do about the problem, i.e., regular voiding habits, sound voiding posture, avoiding holding manoeuvres, etc.
- Lifestyle advice, regarding fluid intake, prevention of constipation, etc.

- Registration of symptoms and voiding habits using bladder diaries or frequency-volume charts
- Support and encouragement via regular follow-up by the caregiver

A success rate of 80% has been described for urotherapy programmes, independent of the components of the programme. However, the evidence level is low as most studies of urotherapy programmes are retrospective and non-controlled.

Specific Interventions

As well as urotherapy, there are some specific interventions, including physiotherapy (e.g., pelvic floor exercises), biofeedback, alarm therapy and neurostimulation. Although good results with these treatment modalities have been reported, there have been no randomized controlled treatment trials (RCTs), so that the level of evidence is low.

In some cases, pharmacotherapy may be added. Antispasmodics and anticholinergics have been shown to be effective, although the level of evidence was low. More recently, a few RCTs have been published. One trial on tolterodine showed safety but not efficacy, while another RCT on propiverine showed both safety and efficacy (**level of evidence: 1**). The difference in results is probably due to study design. Despite the low level of evidence for the use of anticholinergics and antimuscarinics, their use is recommended (**grade of recommendation: B**) because of the large number of studies reporting a positive effect on OAB symptoms.

Although alpha-blocking agents are used occasionally, an RCT showed no benefit. Botulinum toxin injection seems promising, but can only be used off-label.

Definitions:

Levels of Evidence

- **1a** Evidence obtained from meta-analysis of randomized trials
- **1b** Evidence obtained from at least one randomized trial
- **2a** Evidence obtained from at least one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for some of the recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis, treatment, and management of daytime lower urinary tract conditions
- Daytime control of bladder function

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The purpose of these texts is not to be proscriptive in the way a clinician should treat a patient but rather to provide access to the best contemporaneous consensus view on the most appropriate management currently available. European Association of Urology (EAU) guidelines are not meant to be legal documents but are produced with the ultimate aim to help urologists with their day-to-day practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The European Association of Urology (EAU) Guidelines long version (containing all 19 guidelines) is reprinted annually in one book. Each text is dated. This means that if the latest edition of the book is read, one will know that this is the most updated version available. The same text is also made available on a CD (with hyperlinks to PubMed for most references) and posted on the EAU websites

Uroweb and Urosource (www.uroweb.org/index.php?id=388).

Condensed pocket versions, containing mainly flow-charts and summaries, are also printed annually. All these publications are distributed free of charge to all (more than 10,000) members of the Association. Abridged versions of the guidelines are published in European Urology as original papers. Furthermore, many important websites list links to the relevant EAU guidelines sections on the association websites and all, or individual, guidelines have been translated to some 15 languages.

IMPLEMENTATION TOOLS

Foreign Language Translations Pocket Guide/Reference Cards Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Daytime lower urinary tract conditions. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr Chr, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2009 Mar. p. 26-9. [19 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar (revised 2009 Mar)

GUIDELINE DEVELOPER(S)

European Association of Urology - Medical Specialty Society European Society for Paediatric Urology - Medical Specialty Society

SOURCE(S) OF FUNDING

European Association of Urology

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: S. Tekgül (Co-chairman); H. Riedmiller (Co-chairman); E. Gerharz; P. Hoebeke; R. Kocvara; R. Nijman; Chr. Radmayr; R. Stein

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Paediatric Urology Guidelines writing panel have provided disclosure statements on all relationships that they have and that might be perceived to be a potential source of conflict of interest. This information is kept on file in the European Association of Urology Central Office database. This guidelines document was developed with the financial support of the European Association of Urology (EAU). No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance and travel and meeting expenses. No honoraria or other reimbursements have been provided.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Daytime lower urinary tract conditions. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 29-32.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>European Association of Urology Web site</u>.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidelines on paediatric urology. Pocket guideline. Arnhem, The Netherlands: European Association of Urology (EAU); 2009 Mar. 13 p. Electronic copies: Available in <u>English</u> and <u>Russian</u> in Portable Document Format (PDF) from the European Association of Urology Web site. Also available as an e-book form the <u>European Association of Urology Web site</u>.
- EAU guidelines office template. Arnhem, The Netherlands: European Association of Urology (EAU); 2007. 4 p.
- The European Association of Urology (EAU) guidelines methodology: a critical evaluation. Arnhem, The Netherlands: European Association of Urology (EAU); 18 p.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on November 14, 2008. The information was verified by the guideline developer on December 19, 2008. This NGC summary was updated by ECRI Institute on November 16, 2009. The information was verified by the guideline developer on December 23, 2009.

COPYRIGHT STATEMENT

This summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Downloads are restricted to one download and print per user, no commercial usage or dissemination by third parties is allowed.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse[™] (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC

Inclusion Criteria which may be found at http://www.quideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Copyright/Permission Requests

Date Modified: 3/1/2010

